K102107

(510(k) Summary)

SEP 3 2010

Product: OSStaple™ Chill

BioMedical Enterprises, Inc. (BME) intends to introduce an addition to the OSStaple™ line of the OSStaple™ Staple System.

Submitter Information

BioMedical Enterprises, Inc.
14785 Omicron Drive, Ste. 205
San Antonio, Texas 78245
Telephone: (210) 677-0354
Contact: Joe W. Soward

Date Prepared: August 19, 2010

Classification name: Single/multiple component metallic bone fixation appliances and accessories

Common/Usual Name:	Bone Staple
Proprietary Name:	OSStaple™ Chill
Product Code:	JDR

Intended Use:

The OSStaple™ Chill is indicated for:
Fracture and osteotomy fixation and joint arthrodesis of the hand and foot and,
Fixation of proximal tibial metaphysis osteotomy.

Device Description and Testing

The OSStaple™ Chill is a nitinol implant that comes in a range of sizes and models for use in extremity bone fragment fixation, osteotomy fixation, and joint arthrodesis. The implant is delivered to the operating room in an "open" martensitic state. The implant is then transformed by body heat after insertion, and contracts to a "closed" austenitic state.

The OSStaple™ Chill differs from the OSStaple™ in that the staples do not require any external heating; they are completely transformed by body heat. The OSStaple™ Chill also includes staples with smooth and barbed legs to achieve increased pull-out resistance. All other characteristics of the implant are identical to the OSStaple™ predicate.

Bench testing of the OSStaple™ Chill showed that the implants remain in their open martensitic state at operating room temperatures (20°C - 24°C), and fully transform to their closed shape by body temperature (37°C). Testing also showed that both the smooth and barbed versions of the OSStaple™ Chill achieve equivalent or superior pull-out resistance to the OSStaple™.

Substantial Equivalence:

The OSStaple™ Chill is substantially equivalent to the predicate BME OSStaple™ cleared by the FDA in K993714.

The FDA has classified these equivalent devices as Class II devices (e.g. 21 CFR 888.3030). The OSStaple™ Chill is a Class II medical device.

(Signature)

Joe W. Soward
Director, Quality Assurance and Regulatory Affairs
BioMedical Enterprises, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomedical Enterprises Inc.
% Mr. Joe Soward
Director, Quality Assurance and Regulatory Affairs
14785 Omicron Drive, Suite 205
San Antonio, Texas 78245

SEP 3 2010

Re: K102107
Trade/Device Name: OSStaple™ Chill
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: August 9, 2010
Received: August 10, 2010

Dear Mr. Soward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

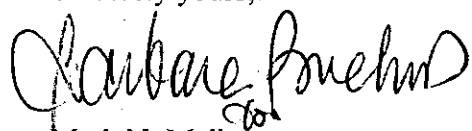
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102107

Device Name: OSStaple™ Chill

Indications for Use

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The OSStaple™ Chill is indicated for:

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot and,
- Fixation of proximal tibial metaphysis osteotomy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K102107 Barbara Ruehl for NXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102107

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